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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Jan Vandeputte

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EXAMINER

MERCIER, MELISSA S

ART UNIT

PAPER NUMBER

1615

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/519,295	Applicant(s) VANDEPUTTE, JAN	
	Examiner MELISSA S. MERCIER	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7-14 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7-14, 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 22, 2008 has been entered.

Claims 1, 7-14, and 16-21 are pending in this application. Claims 20-21 remain withdrawn from consideration as reading on a non-elected invention. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 7-8, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundmark (US Patent 6,174,535).

Lundmark teaches dispersing honey in polyglycerylmethacrylate, and mixing the honey and the polyglycerylmethacrylate for a sufficient period of time to form a hydrated honey gel polymeric composition" (column 2, lines 54-56). Lundmark discloses, "the

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products of the present invention may be formulated into lotions, shampoos, hair conditioners, sunscreens, insect repellants and the like” (column 4, lines 60-63).

Lundmark additionally discloses, a desirable component for use is a glycol. The glycol adds humectant properties to the composition (column 4, lines 18-20). Lundmark discloses, “ the preferred polyglycerylmethacrylate is Lubrajel CG, a clathrate formed by the reaction of glycerin and methylmethacrylate” (column 3, lines 11-24). The presence of glycerin would exhibit the humectant qualities claimed in the instant claim.

Regarding claims 8, Lundmark’s Example II discloses 3 formulations of their composition, each comprising between 26.00% and 29.00% honey (column 5, line 18).

Regarding Claims 16, the prior art is silent as to the peroxide number of honey and the LPS content. It is the examiners position that these properties are inherent properties of honey and therefore, would be present in the prior art teachings.

The instant claims differ from the references only in the specific percentage selected for the compositions. However, It would have been deemed prima Facie obvious to one having ordinary skill in the art at the time of the invention to optimize the percentage of humectants, polymeric gel based on acrylic monomers, honey, polymer, and water, to prepare a composition containing honey for the topical treatment of wounds because the determination of a specific percentage having the optimum therapeutic effect is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the active compounds. Therefore, the invention as Whole has been prima face obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues Lundmark discloses a honey preparation for cosmetic treatment of keratinous substrates, wherein the honey is a preferred source of liquid polysaccharide. Furthermore, Lundmark discloses other possible sources of liquid polysaccharide such as high fructose corn syrup. Thus, Lundmark *does not* teach or suggest a honey-based wound treatment...wherein the honey has a peroxide number of more than 5 ug/g honey/hour, because Lundmark teaches a preparation comprising honey that can be substituted with corn syrup. And, given corn syrup would not provide the peroxide taught by the present application, in this way, Lundmark teaches *away* from the presently claimed invention. The examiner respectfully disagrees with Applicants conclusion that Lundmark teaches away from the claimed invention. While Lundmark may disclose additional liquid polysaccharides, the use of honey is disclosed, and therefore reads on the instant claims. Applicant is directed to MPEP 2123, which discloses patents are relevant as prior art for all they contain. Furthermore, in Applicants presented arguments, Applicant argues that the concentration of honey will determine its peroxide number. Since Lundmark discloses percentages of honey within the claimed ranges of Applicant, absent a showing to the contrary, it is the position of the examiner that the honey would have the same properties as instantly claimed.

Applicant further argues Lundmark does not disclose his composition to be used as a treatment for wounds. It is noted that Applicant is claiming a composition and not a

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method of treatment in the rejected claims; therefore, the future intended use or function of the composition does not hold patentable weight.

Claims 9-10, 12, and 19, rejected under 35 U.S.C. 103(a) as being unpatentable over Lundmark (US Patent 6,174,535) in view of Stout (US Patent 4,671,267).

Lundmark's teachings are described above and applied in the same manner.

Lundmark does not disclose the composition can be used for the healing of wounds, the thickness of the application of the composition, and the gel being a 50% acrylamide, 50% water mixture.

Regarding Claim 9, Stout discloses, "improved therapy members useful for treating of sprains, muscle aches, orthopedic and skin injuries such as burns and other wounds are provided which make use of a pliable, self-sustaining, moisture sorbing gel including a humectants such as glycerin entrapped within a synthetic resin polymer matrix (e.g., a matrix containing acrylic acid or acrylamide monomer moieties)" (abstract). Stout further discloses, "the gel material can be applied directly to injured skin to in effect create a temporary skin with ideal air permeability" (abstract).

Regarding Claim 12, Stout discloses in Table II and Example 4, a 50% acrylamide in water solution. The examiner is interpreting this to be a mixture that is 50% acrylamide and 50% water.

Regarding Claim 19, Stout discloses, "the preferred gel material provides an excellent dressing for the treatment of burned or otherwise injured skin. In this case a thin (for example from about 0.05 to 0.5 inches) layer of the gel material is hermetically

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sealed in a sterile package, and in use is simply directly applied to injured skin, without any intermediate cloth covering or the like" (column 3, lines 24-45). 0.05 to 0.5 inches converts to approximately, 1.27mm to 12.7mm, which overlaps the claimed range.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teaching of Lundmark with the teachings of Stout in order to form 'a gel material that can be applied directly to injured skin to in effect create a temporary skin with ideal air permeability. Furthermore, the moisture absorbing and desorbing properties of the gel create a moisture equilibrium between the gel, damaged skin and the atmosphere, thus promoting rapid healing" (abstract).

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant's arguments regarding Lundmark are discussed above. Applicants has not provided any arguments regarding the teachings of Stout other than stating one would not be motivated to combine a cosmetic lotion containing honey with the wound gel of Stout. Applicant is reminded that arguments of council do not take the place of evidence when evidence is needed. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lundmark (US Patent 6,174,535) in view of Stout (US Patent 4,671,267) and further in view of Dell (US Patent 4,542,012).

Lundmark's teachings as they apply to Claim 1 are described above.

Lundmark does not disclose the use of acrylamide or analog compounds consisting of diacetone acrylamide, vinyl lactam, N-alkylated acrylamide, N,N-diakylated acrylamide, N-vinylpyrrolidone, or acryloylmorpholin.

Stout teaches the use of acrylamide as a monomer, however, Stout does not teach the use of analog compounds.

Dell discloses, "a dermatologically acceptable, film-forming composition which comprises a film-forming polymer and, as a broad spectrum antimicrobial agent. The composition when applied to the skin from a fugitive solvent form a substantially water-insoluble, tack-free, flexible film, which adheres to the skin, releases the antimicrobial agent. (abstract).

Dell disclosed the polymer being "a polyvinylpyrrolidone polymer which is the free-radical-polymerization reaction product of at least N-vinylpyrrolidone and a vinyl-functional compound" (column 2, lines 43-47).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have expanded upon the teachings of Lundmark and Stout, with the polymer taught by Dell, in order to form "a good film-forming composition should be dermatologically-acceptable and capable of application to skin conveniently as a solution in a dermatologically-acceptable, volatile solvent. The film resulting from

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application of such a solution should be bacteria-impermeable, water-insoluble, nontacky and should permit facile transmission of water vapor there through. It should adhere suitably to skin and be capable of releasing the antimicrobial agent onto the skin over a period of time to promote asepsis for a suitably long period of time" (column 2, lines 3-24).

The Applicant would have a reason expectation of success since N-vinylpyrrolidone is commonly used as a film-forming polymer in cosmetic formulations. It would be within the knowledge of one of ordinary skill in the art to substitute it for an acrylic polymer used for the same function.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant's arguments regarding Lundmark and Stout are discussed above. Applicant has not provided any arguments regarding the teachings of Dell other than stating, in contrast to amended claim 1, Dell does not disclose or suggest a *honey-based wound treatment...*, wherein the honey has a peroxide number of more than 5 ug/g honey/hour. The polymer of Dell in combination with the cosmetic lotion of Lundmark and the wound gel of Stout would not provide for the honey-based preparation having the peroxide concentration of the presently claimed invention. Applicant is reminded that arguments of council do not take the place of evidence when evidence is needed. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Claims 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundmark (US Patent 6,174,535) in view of Trenzeluk (US Patent 4,857,328).

Lundmark's teachings are described above and applied in the same manner.

Lundmark does not disclose the use of antioxidants, transretinoic acid and/or derivatives and precursors thereof, polyunsaturated fatty acids, n-hexacosanol, bis(maltolato)oxo-vanadium(IV), aloe vera, and thickeners. Lundmark also does not disclose a percentage of additives.

Trenzeluk discloses "a skin therapeutic mixture is useful for the alleviation of certain skin disorders such as acne, psoriasis, burns, pimples, blackheads, and open sores: the therapeutic agent being the extract from the dried leaves of the aloe vera plant; the skin therapeutic mixture comprises about 7.4% by weight of the extract from the dried leaves of the aloe vera plant as the therapeutic agent" (abstract).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have added aloe vera to a skin care composition, since aloe is well known in the art for its soothing effects, fragrance, and healing qualities.

The applicant would have a reason expectation of success since the use of aloe vera is well known in the art for the same reasons and qualities applicant is claiming.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant's arguments regarding Lundmark are discussed above. Applicants has not provided any arguments regarding the teachings of Trenzeluk other than stating, in

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contrast to amended claim 1, Trenzeluk does not disclose or suggest a *honey-based wound treatment.., wherein the honey has a peroxide number of more than 5 ug/g honey/hour*. Applicant is reminded that arguments of council do not take the place of evidence when evidence is needed. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundmark (US Patent 6,174,535) in view of Hymes et al. (US Patent 4,307,717).

Lundmark's teachings as they apply to Claim 1 are described above.

Lundmark does not disclose the honey being sterilized with the use of gamma rays.

Hymes discloses a liquid absorbent, adhesive bandage, in which the combination of the mixture is then subjected to irradiation (usually gamma rays) usually to 2.5 mega rads for sterilization (column 2, lines 65-67).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have used the sterilization method taught by Hymes on the composition taught by Lundmark in order to make a composition which is suitable for direct contact with the skin to cover surgical wounds or burn tissue" (Hymes, column 2, lines 23-27).

Applicant would have a reasonable expectation of success in the sterilization of a composition using gamma rays, since irradiation with gamma rays is known in the art as being effective.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant's arguments regarding Lundmark are discussed above. Applicant has not provided any arguments regarding the teachings of Hymes other than stating, in contrast to amended claim 1, Hymes does not disclose or suggest a *honey-based wound treatment.., wherein the honey has a peroxide number of more than 5 ug/g honey/hour*. Applicant is reminded that arguments of counsel do not take the place of evidence when evidence is needed. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 7:30am-4pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/Michael P Woodward/
Supervisory Patent Examiner, Art
Unit 1615